MAR - 8 2001

K003820

510-528 S. Vermont Avenue Glendora, CA 91741 (626) 914-2891 FAX (626) 914-2285

Ref: 510(k) Premarket Notification Summary

To: Document Control Clerk:

This is to notify you of the intention of OASIS Medical, Inc. to manufacture and market the following device:

Disposable CB-PE Microkeratome Blades

Establishment Registration Number: 2083373

This 510(k) summary of safety and effectiveness for the OASIS Microkeratome Blades is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92, and follows the Office of Device Evaluation guidance concerning the presentation and content of a 510(k) summary.

1. Submitter's name, address, telephone number, contact person, and date the summary was prepared:

   a. **Applicant:** OASIS Medical, Inc.
   514 South Vermont Avenue
   Glendora, CA 91741

   b. **Telephone Number:** (626) 914-2891

   Facsimile Number: (626) 914-9372

   c. **Contact Person:** Yvonne Fernandez- RA/QA Director

   d. **Date Summary Prepared:** 11/30/00

2. Name of the Device, including trade name, the common or usual name, and the classification:

   a. **Trade/Proprietary Name:** Disposable CB-PE Microkeratome Blades

   b. **Common/Usual Name:** Keratome Blade

   c. **Classification Name:** Keratome (Blade Only) - 21CFR §886.4370

   d. **Classification:** Class I

   e. **Product Code:** 86 HNO

   f. **Classification Panel:** Ophthalmic

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3. Identification of legally marketed devices to which equivalence is being claimed:

The OASIS Medical, Inc. Disposable CB-PE Microkeratome Blades are substantially equivalent in design, material and function to the devices as marketed by:

Company	Device	510(k) Number
Moria, S.A.	CB Microkeratome Blade Only	K981741

4. Description of the Device:

The OASIS Disposable CB-PE Microkeratome Blades are replacement stainless steel blades for the CB Microkeratome blade. The Disposable CB-PE Microkeratome Blades are made of 400 Series Stainless Steel, packaged and sterilized using the same methods. The OASIS Disposable CB-PE Microkeratome Blades are single-use, disposable blades.

Certification of Safety and Effectiveness:

When used according to the keratome manufacturer's instructions, there are no adverse safety indications the 0416 blade.

Sterilization Methodology:

All blades are sterilized by exposure to ethylene oxide to a Sterilization Assurance Level (SAL) of 10^{-6} according a validated process in compliance with EN 550.

Labeling:

The pouch will indicate OASIS name, address, product identification, lot number, sterilization notes, single use, and federal law statements.

5. Intended Use for the Device:

The OASIS CB-PE Microkeratome Blades (Catalog #0416) are designed as replacement blades for the CARRIAZO BARRAQUER Microkeratome for lamellar resection of the cornea.

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6. Summary of the technological characteristics of the submitted device compared to predicate devices:

CB-PE Blade – Summary of Technological Characteristics of Device Compared to Predicate Device‡ [Section 807.92(a)(6)] - K981741

Characteristics	PD‡ - CB Microkeratome Blade	Oasis 0416 CB-PE
Intended Use	As indicated	Same
Target population	As indicated	Same
Performance	Compatibility with CB Microkeratome	Same
Blade Material	Low carbon stainless steel	Same
Biocompatibility	For Stainless Steel Blades	Same
Mechanical Safety	Assured	Same

Performance Tests and Conclusions:

1. Dimensional Equivalency Test – Physical measurements of the predicate device are substantially equivalent to the measurements of blades manufactured by OASIS Medical, Inc.

2. Sharpness Tests – Sharpness tests show that the OASIS CB-PE blades (0416) perform as well as the predicate device.

3. Fit into the CB Microkeratome has been tested and shown to be acceptable.

4. Non-clinical testing on porcine eyes resulted in corneal lamellar sections equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

Ms. Yvonne Fernandez
RA/QA Director
OASIS Medical, Inc.
514 South Vermont Ave.
Glendora, CA 91741

Re: K003820
Trade Name: Disposable CB-PE Microkeratome Blades
Regulatory Class: Class I
Product Code: 86 HNO, Keratome, AC - Powered
Regulation: 21CFR 886.4370, Keratome
Dated: December 8, 2000
Received: December 11, 2000

Dear Ms. Fernandez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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OASIS Medical, Inc.
Disposable CB-PE (Precision Edge) Microkeratome Blades
Indications For Use

510(k) Number (if known): K003820

Device Name: Disposable CB-PE Microkeratome Blades

The OASIS Disposable CB-PE (Precision Edge) Microkeratome Blade (Catalog #0416) is designed as a replacement blade for the CARRIAZO BARRAQUER Microkeratome for lamellar resection of the cornea.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003820

Prescription Use: X OR Over The Counter Use: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)